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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,118	04/12/2004	Bjorn A.J. Angelsen	4215-17	3518

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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,118

Applicant(s)

ANGELSEN ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121.

Group I: Claims 1, 2, and 4-12 drawn to a method for increasing the reaction velocity of chemical binding of DNA to DNA probe molecules in a microarray or gene chip system, where ultrasound is applied to a solution containing the DNA molecules, classified in class 702, subclass 019. If this Group is elected, then the below summarized specie election is also required.

Group II: Claims 3, 13-16 drawn to a method of increasing the processing speed of DNA binding to DNA-probe molecules on a microarray, where ultrasound is applied in the washing process after hybridization, classified in class 702, subclass 019. If this Group is elected, then the below summarized specie election is also required.

The inventions are distinct, each from the other because of the following reasons:

The invention of Group I is directed to a method for increasing the reaction velocity of chemical binding of DNA to DNA probe molecules in a microarray or gene chip system for identification and quantification purposes. Group I uses ultrasound for increasing the reaction kinetics of DNA-probe to target binding, which occurs during the hybridization process. The invention of Group II is directed to a method for increasing the processing speed of DNA binding to DNA-probe molecules on a microarray. In contrast, Group II uses ultrasound for removing superfluous DNA (loose probe) during the washing process, which occurs post-hybridization. The subject matter of Group I is directed to a specific means of hybridization enhancement,

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whereas the subject matter of Group II is directed to a specific post-hybridization means of increasing processing speed and specificity. Thus, the search for both Groups together would present an undue search burden as they are directed to systems and/or methods that are generally distinct and separate in genetic information analysis systems.

SPECIE ELECTION REQUIREMENT FOR GROUPS I and II

This application contains claims directed to patentably distinct species of the claimed invention. If Group I is elected, the applicant is further required to make two of the following specie elections for purposes of examination (i.e. select between Specie I-A or Specie I-B and Specie II-A or Specie II-B). If Group II is elected, the applicant is further required to make one of the following specie elections for purposes of examination (i.e. select Specie II-A or Specie II-B).

Specie I-A: Method as set forth in Group I for identification and quantification of GENE EXPRESSION.

Specie I-B: Method as set forth in Group I for identification and quantification of SINGLE NUCLEOTIDE MUTATIONS.

Specie II-A: Method as set forth in Group I or II where ultrasound is applied in DIRECT CONTACT with the microarray or gene chip system (i.e. ultrasound vibrations are generated directly in the substrate and coupled into the DNA solution).

Specie II-B: Method as set forth in Group I or II where ultrasound is applied in ACOUSTIC CONTACT with the microarray gene chip system (i.e. ultrasound vibrations are generated in the substrate via an acoustic coupling medium).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **Claims 1, 2, 5, 6, 8, 11, and 12** (from Group I) and **Claims 3, 14, and 16** (from Group II) are generic to all of the above species. The species are distinct due to the specific use of ultrasound in a microarray system, and the method by which ultrasound is administered in that system. The use of the instantly claimed invention for the identification and quantitation of *gene expression* is different from the identification and quantitation of *single nucleotide mutations*. The method of quantitation in gene expression involves the use of a probe to determine an array of active genes (i.e. there is no target). In the later, a probe is used to determine the presence of mutations which are expected at specific defined positions (i.e. the

target is known). These methods of quantitation are different and distinct, and thus present a clearly distinct search burden which is undue if searched together.

Furthermore, these species are distinct due to the method by which ultrasound is applied to the microarray system. In the direct contact setup, ultrasound transducers emit sound waves directly into the substrate. In contrast, in the acoustic contact setup, ultrasound transducers emit sound waves into the substrate via an acoustic coupling medium. Not only are these different physical and mechanical setups, there are a large number of materials available for use as contact mediums in the acoustic contact setup and each has different acoustic properties. Thus, there is a clearly distinct search burden which is undue if searched together.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H. Marschel 8/14/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER